



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2003

Sola Medical Devices, LLC
c/o Mr. Greg Holland
Regulatory Consultant
Regulatory Specialists, Inc.
3722 Ave. Sausalito
Irvine, CA 92606

Re: K022078

Trade Name: Sola Counter-Pulsating Device
Regulation Number: 21 CFR 870.5225
Regulation Name: External Counterpulsating Device
Regulatory Class: Class III (three)
Product Code: DRN
Dated: October 24, 2002
Received: October 29, 2002

Dear Mr. Holland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

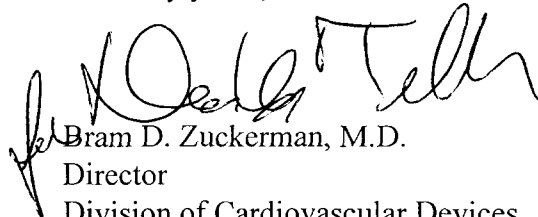
Page 2 – Mr. Greg Holland

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K022078

Device Name: Sola Counter-Pulsating device

Indications For Use:

This device can be used for the treatment of:

The Sola Counter-Pulsating device is a non invasive external counterpulsation device intended for use in the treatment of patients with stable angina pectoris, acute myocardial infarction, cardiogenic shock and congestive heart failure.

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K022078

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)